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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/625,164	07/23/2003	Eddie Reed	27497/2002	8006
29932	7590	12/13/2007		
PAULA EVANS/ C/O SONNENSCHN NATH & ROSENTHAL LLP P.O. BOX 061080 WACKER DRIVE STATION, SEARS TOWER CHICAGO, IL 60606-1080			EXAMINER HOEKSTRA, JEFFREY GERBEN	
			ART UNIT 3736	PAPER NUMBER
			MAIL DATE 12/13/2007	DELIVERY MODE PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

## Office Action Summary

Application No.

10/625,164

Applicant(s)

REED ET AL.

Examiner

Jeffrey G. Hoekstra

Art Unit

3736

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 03 October 2007.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 25-32 and 34-38 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 25-32 and 34-38 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 19 April 2006 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)          | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____                                      |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)          | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____  | 6) <input type="checkbox"/> Other: _____                          |

## **DETAILED ACTION**

### ***Continued Examination Under 37 CFR 1.114***

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 10/03/2007 has been entered.

### ***Notice of Amendment***

2. In response to the amendment filed on 10/03/2007, canceled claim(s) 1-24 and 33, amended claim(s) 25, 26, and 34 new claim(s) 35-38 is/are acknowledged. The current rejections of the claim(s) 25-34 is/are *withdrawn*. The following new and reiterated grounds of rejection are set forth:

### ***Drawings***

3. In response to Applicant's assertions that new drawings were submitted with the amendment filed 10/03/2007, the Examiner notes the drawings did not appear to be present in the record. Thus it remains that:

4. The drawings were received on 04/19/2006. These drawings are --*not acceptable*--.

5. The drawings are objected to because they appear to be copies of color photographs (see paragraph 9) and they are illegible informal images. Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office

action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. The figure or figure number of an amended drawing should not be labeled as "amended." If a drawing figure is to be canceled, the appropriate figure must be removed from the replacement sheet, and where necessary, the remaining figures must be renumbered and appropriate changes made to the brief description of the several views of the drawings for consistency. Additional replacement sheets may be necessary to show the renumbering of the remaining figures. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the examiner does not accept the changes, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

6. Color photographs and color drawings are not accepted unless a petition filed under 37 CFR 1.84(a)(2) is granted. Any such petition must be accompanied by the appropriate fee set forth in 37 CFR 1.17(h), three sets of color drawings or color photographs, as appropriate, and, unless already present, an amendment to include the following language as the first paragraph of the brief description of the drawings section of the specification:

The patent or application file contains at least one drawing executed in color. Copies of this patent or patent application publication with color drawing(s) will be provided by the Office upon request and payment of the necessary fee.

Color photographs will be accepted if the conditions for accepting color drawings and black and white photographs have been satisfied. See 37 CFR 1.84(b)(2).

***Claim Objections***

7. Claim 25 is objected to because of the following informalities: the positive recitation in line 1 of "for detecting the presence" should apparently read "for detecting a presence". Appropriate correction is required.

8. Claim 27 is objected to because of the following informalities: the positive recitation in line 2 of "the form" should apparently read "a form". Appropriate correction is required.

9. Claim 36 is objected to because of the following informalities: the positive recitation in line 2 of "the length" should apparently read "a length". Appropriate correction is required.

10. Claim 37 is objected to because of the following informalities: the positive recitation in line 2 of "the group" should apparently read "a group". Appropriate correction is required.

***Claim Rejections - 35 USC § 112***

11. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

12. Claim 34 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

13. Claim 34 provides for the use of a method for detecting high risk HPV, but, since the claim does not set forth any steps involved in the method/process, it is unclear what method/process applicant is intending to encompass. A claim is indefinite where it merely recites a use without any active, positive steps delimiting how this use is actually practiced.

***Claim Rejections - 35 USC § 101***

14. 35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

15. Claim 34 is rejected under 35 U.S.C. 101 because the claimed recitation of a use, without setting forth any steps involved in the process, results in an improper definition of a process, i.e., results in a claim which is not a proper process claim under 35 U.S.C. 101. See for example *Ex parte Dunki*, 153 USPQ 678 (Bd.App. 1967) and *Clinical Products, Ltd. v. Brenner*, 255 F. Supp. 131, 149 USPQ 475 (D.D.C. 1966).

***Claim Rejections - 35 USC § 102***

16. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

17. Claims 25-27 and 34-38 are rejected under 35 U.S.C. 102(e) as being anticipated by Edens et al. (US 6,521,190 B1, hereinafter Edens).

18. Edens discloses a method for detecting human papilloma virus (HPV) in a vaginal specimen (column 1 line 5 - column 2 line 30, column 4 lines 28-51), wherein the specimen contains cervical cells and few endocervical cells (column 1 line 5 - column 2 line 30), said method comprising:

- obtaining the specimen (abstract, column 3 lines 7-17) with a device (100,300) (as best seen in Figure 2) comprising a collection element (200) (as best seen in Figure 2) and a shield comprising an outer tube (110) surrounding the collection element (as best seen in Figures 1A and 2),
  - wherein the collection element comprises an inner tube (220) and a brush (210) attached to the inner tube (as best seen in Figure 2),
  - wherein the brush inherently has a brush longitudinal axis and comprises bristles (210) (column 3 lines 12-17) that are substantially perpendicular to the brush longitudinal axis (as best seen in Figure 2),
  - wherein the bristles comprise a flexible plastic material (column 4 lines 23-28) selected from a group consisting of: polyethylene, polyurethane, polyvinyl chloride, polysiloxanes, and nylon,
  - wherein the inner tube inherently has an inner tube longitudinal axis and the inner tube longitudinal axis runs parallel to the brush longitudinal axis (as best seen in Figure 2),

- wherein the inner tube element and the outer tube element are cylindrical in shape (as best seen in Figure 2),
  - wherein an inner tube length and an outer tube length are roughly equal (as best seen in Figure 2), and
  - wherein the device does not use an absorbent material to collect the sample (column 1 line 5 - column 2 line 30, column 4 lines 52-63); and
- detecting the presence of HPV in the specimen (column 1 line 5 - column 2 line 30, column 4 lines 28-51).

***Claim Rejections - 35 USC § 103***

19. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

20. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).



21. Claims 28-32 are rejected under 35 U.S.C. 103(a) as being unpatentable over Edens in view of Zavada et al (US 2003/0049828 A1, hereinafter Zavada). Edens teaches the claimed invention, as set forth above, except for expressly disclosing specimen testing including (a) extracting DNA and amplifying HPV nucleic acid to detect the presence of HPV and (b) contacting the specimen with a multiple polypeptides that bind to a HPV antibody or protein and subsequent detection of the bound antibody or protein in the specimen. Zavada teaches specimen testing including (a) extracting DNA and amplifying HPV nucleic acid (paragraphs 33-34) to detect the presence of HPV and (b) contacting the specimen with a multiple polypeptides that bind to a HPV antibody (paragraph 35) or protein (paragraph 40) and subsequent detection of HPV (paragraph 17) in the specimen. All the claimed elements were known in the prior art and one skilled in the art could have combined the elements as claimed by known methods with no change in their respective functions, and the combination would have yielded predictable results to one of ordinary skill in the art at the time of the invention. All of the component parts are known in Edens and Zavada. The only difference is the combination of the component parts into a single device. Thus, it would have been obvious to one having ordinary skill in the art at the time of the invention to combine the components as taught by Edens with the components as taught by Zavada to achieve the predictable results of detecting HPV with the use of a collection element and various detection methods.

***Response to Arguments***

22. Applicant's arguments with respect to claims 25-32 and 34-38 have been considered but are moot in view of the new ground(s) of rejection.

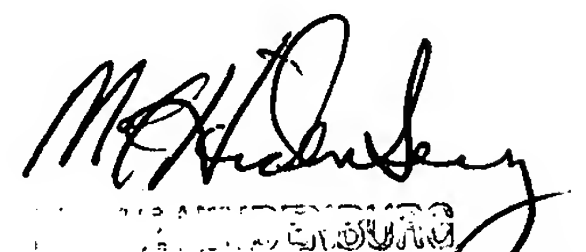
***Conclusion***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jeffrey G. Hoekstra whose telephone number is (571)272-7232. The examiner can normally be reached on Monday through Friday, 8:00 a.m. to 5:00 p.m. EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Max F. Hindenburg can be reached on (571)272-4726. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/J.H./  
Jeff Hoekstra  
Examiner, Art Unit 3736

  
MAX F. HINDENBURG  
JUL 16 2010  
EBC CENTER 0700